

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SMITH KLINE & FRENCH)	
LABORATORIES LIMITED and)	
SMITHKLINE BEECHAM)	
CORPORATION d/b/a)	
GLAXOSMITHKLINE,)	
)	
Plaintiffs,)	Civil Action No. 05-197
)	
v.)	
)	
TEVA PHARMACEUTICALS USA, INC.,)	
)	
Defendant.)	
)	

STIPULATED PROTECTIVE ORDER

WHEREAS Plaintiffs SmithKline & French Laboratories Limited and SmithKline Beecham Corp., d/b/a GlaxoSmithKline, (collectively "GSK") and Defendant Teva Pharmaceuticals USA, Inc. ("Teva") are parties to the above-referenced Civil Action No. 05-197 ("the Action");

WHEREAS discovery in the Action may involve the disclosure of certain documents, things and information in the possession, custody or control of GSK, Teva, or non-parties, which constitute or contain trade secrets or other confidential research, development, or commercial information;

WHEREAS such confidential information must be protected in order to preserve the legitimate business interests of the parties or non-parties;

WHEREAS the parties have, through counsel, stipulated to the entry of this Protective Order for the purpose of advancing the progress of the Action and to prevent unnecessary

dissemination or disclosure of such confidential information; and

WHEREAS the parties have established good cause for entry of this Protective Order;

THEREFORE, for good cause shown, pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, all discovery and other materials exchanged by the parties or non-parties, or filed with the Court, in the Action shall be provided subject to the following conditions:

1. This Protective Order shall apply to all documents and portions thereof, things, or any other form of evidence or information subject to discovery or that can be protected under Fed. R. Civ. P. 26(c) in the Action that are owned, possessed, or controlled by a party or a non-party ("Producing Party") and that contain the Producing Party's trade secrets or other confidential research, development, or commercial information, and all information derived therefrom, including, without limitation, documents, things, deposition testimony, interrogatory answers, answers to requests for admissions, and other discovery materials that are provided to or received by another party or non-party in the Action ("Receiving Party"), whether produced informally or in response to formal methods of discovery ("Confidential Material").

2. It shall be the duty of the Producing Party to give notice, in the manner set forth in Paragraph 3, below, of the Confidential Material designated to be covered by this Protective Order. The duty of the Receiving Party or Parties and of all other persons bound by this Protective Order to maintain the confidentiality of Confidential Material so designated shall commence with such notice.

3. Each page of any material the Producing Party wishes to designate as Confidential Material must be labeled with the legend "CONFIDENTIAL" at the time the document or thing, or a copy thereof, is provided to the Receiving Party. In the case of Confidential Material contained in or on media other than paper, the Producing Party shall affix such a label to the

information or use its best efforts to identify the information as Confidential Material.

4. The failure by a Producing Party to designate specific documents or materials as containing Confidential Material shall not be deemed a waiver in whole or in part of a claim of confidentiality as to such documents or materials. Upon notice to the Receiving Party of such failure to designate, the Receiving Party shall cooperate to retrieve disseminated originals and/or copies, restore the confidentiality of the inadvertently disclosed information, and restrict further dissemination of the disclosed information beyond those persons authorized to review such information pursuant to Paragraph 9.

5. With respect to all documents or things provided for inspection by a Producing Party's counsel, designation as Confidential Material need not be made until copies of the documents or things are produced after inspection and selection by counsel. Making documents or things available for inspection shall not constitute a waiver of any claim of confidentiality or attorney-client privilege, and all materials provided for inspection by a Producing Party's counsel shall be treated as though designated as Confidential Material at the time of the inspection.

6. All testimony provided in a deposition and deposition exhibits will be treated as Confidential Material for twenty-one (21) days from the day the Producing Party received the deposition transcript. At the expiration of the twenty-one-day period, the transcript and exhibits will no longer be treated as Confidential Material unless: (1) at the deposition, counsel for the Producing Party identifies on the record certain portions of the deposition transcript and/or exhibits that contain Confidential Material, or (2) counsel for the Producing Party provides written notice to counsel for the Receiving Party identifying the portions of the transcript and/or exhibits that contain Confidential Material. All counsel receiving such notice shall be responsible for marking the copies of the designated transcript in their possession or under their

control as directed by Producing Party. Deposition exhibits previously designated as Confidential Material do not need to be re-designated to retain their protection under this Protective Order.

- a. At any deposition session, when counsel for a Producing Party deems that the answer to a question will result in the disclosure of Confidential Material, counsel shall have the option, in lieu of or in addition to taking other steps available under the Federal Rules of Civil Procedure, to direct that the testimony shall be treated as Confidential Material and subject to this Protective Order. Counsel for the Producing Party whose Confidential Material is involved may also request that all persons other than the witness and individuals who may have access to such designated Confidential Material under this Order, leave the deposition room during the confidential portion of the deposition. The failure of such other persons to comply with a request of this type shall constitute substantial justification for counsel for the Producing Party to advise the witness that the witness need not answer the question.
- b. Deposition transcripts containing testimony with designated Confidential Material shall be prominently marked on the front page with a statement that provides "THIS DEPOSITION TRANSCRIPT CONTAINS CONFIDENTIAL MATERIAL THAT IS SUBJECT TO PROTECTIVE ORDER." A deponent may review his/her own transcript designated as containing Confidential Material to ensure that it is accurate and complete, but no deponent (other than individuals who may have access to

Confidential Material under this Order) may retain or copy any portion of the transcript of the deposition that contains Confidential Material without permission of the Producing Party.

7. Confidential Material shall include: (a) all copies, extracts, and complete or partial summaries prepared from such documents, things, or information that are designated Confidential Material; (b) portions of deposition transcripts and exhibits thereto that contain, summarize, or reflect the content of any such documents, things, or information; (c) portions of briefs, memoranda, or any other writings filed with the Court and exhibits thereto that contain, summarize, or reflect the content of any such documents, things, or information; and (d) deposition testimony designated in accordance with Paragraph 6, above.

8. Each party and all other persons bound by the terms of this Protective Order shall use any material designated Confidential Material by a Producing Party other than itself only for the purpose of this Action (including any appeal), and not for any other purpose.

9. Only the following persons shall have access to or retain material designated as Confidential Material:

- a. The Court and its official personnel;
- b. Outside counsel for a party. For the purposes of this Protective Order, "Outside Counsel" means attorneys for the law firms retained by the parties for this Action, including paralegals, office clerks, secretaries, and other support staff assisting those attorneys working on this case;
- c. Provided that the procedure described in Paragraph 10 below is followed, outside experts and consultants retained by the Receiving Party's Outside Counsel to assist in this litigation (and the experts' or consultants' staff

whose duties and responsibilities require access to such materials), who are not past or present full-time employees of the Receiving Party or of an affiliate of the Receiving Party or any other party;

- d. Court reporters and translators:
- e. Outside litigation support personnel, including contract attorneys, retained by Outside Counsel to assist in the preparation and/or litigation of the Action;
- f. Any other person agreed to by the parties; and
- g. The parties agree that each side may identify no more than three in-house attorneys who may review Confidential Material subject to the conditions and procedures set forth in Paragraphs 9.h and 9.i below except that in no event shall access to Confidential Material of the Producing Party be provided to counsel for another party who is involved in or directly advises or supervises the prosecution of patents related to the subject matter of the patents-in-suit. Subject to Paragraph 9.h., at this time the parties agree that the following in-house attorneys may review Confidential Material:

For GSK: 1) Edward Gimmi, Esq
 2) Thomas Smith, Esq.
 3) James Kellerman, Esq.

For Teva: 1) Richard Egosi, Esq.
 2) David Stark, Esq.
 3) Sean Haney, Esq.

- h. If any of the individuals named in Paragraph 9.g terminates his/her position or no longer retains any responsibility with respect to this

litigation, a reasonable substitution (from in-house counsel) may be made for such named individual, upon notice to and consent of opposing counsel, such consent not to be unreasonably withheld. Any such substitution must meet the requirements of Paragraphs 9.g and 9.h, and opposing counsel shall have five (5) business days to object to such substitution. Moreover, to the extent that the responsibilities of any in-house counsel who has access to Confidential Material under this Protective Order change such that the individual is involved in or directly advises or supervises the prosecution of patents related to the subject matter of the patents-in-suit or the individual assumes substantial responsibility for research and development activities related to the subject matter of the patents-in-suit, counsel for the party who designated such individual shall promptly provide written notice to counsel for all other parties.

- i. As a condition precedent to disclosure of Confidential Material to the individuals identified by name (including substitutes) in Paragraph 9.g, each such individual will acknowledge receipt and understanding of this Protective Order and agree to be bound thereby.

10. Before counsel for a Receiving Party may disclose material designated as Confidential Material to a person described in Paragraph 9.c, above, that counsel shall give advance notice as follows: Counsel for the Receiving Party seeking to make the disclosure shall provide written notice (by facsimile followed by a hard copy sent next business day courier) to counsel for the Producing Party and all other parties to this litigation, an executed copy of the

Confidentiality Undertaking attached hereto, and a copy of the curriculum vitae of the person(s) to whom the designated Confidential Material is to be disclosed. Counsel for the Receiving Party need not specifically identify the designated Confidential Material intended to be disclosed. The Producing Party shall have seven (7) business days after receiving that notification within which to object to the proposed disclosure, as provided below; such disclosure shall not occur before the seven-day period for objections has elapsed, and, if any such objection is made, before that objection is resolved, as provided below. Any such objection shall be made in writing (by facsimile followed by a hard copy sent next business day courier) to the counsel for the party seeking to make the disclosure. If the parties are unable to resolve the objection after conferring in good faith pursuant to Fed. R. Civ. P. 26(c), and the Receiving Party indicates that it still intends to disclose the designated Confidential Material to the person or persons in question, the Producing Party must request this Court to issue an order prohibiting the disclosure within fifteen (15) business days of receiving the initial notification under this Paragraph, unless agreed otherwise, in writing, among the counsel involved. The burden of demonstrating good cause for the requested relief shall lie with the Producing Party. A failure to object or file a motion within the requisite time limits shall be deemed a waiver of the objection. Upon a timely objection, and during the periods set forth above and until the issue is resolved by Order of the Court or agreement in writing between the Receiving Party and the Producing Party, no disclosure shall be made to the objected-to person or persons.

11. Any designated Confidential Material, if filed with the Court, shall be filed under seal and shall be made available only to the Court and to persons authorized by the terms of this Protective Order. The party filing any paper that contains, summarizes, or reflects any designated Confidential Material shall file such paper in a sealed envelope, or other appropriately sealed

container, that indicates (a) the case caption; (b) the name of the document if it can be disclosed publicly (otherwise an appropriate title by which the document may be identified on the public docket); (c) the name, address, and telephone number of the person filing the document; (d) the legend CONFIDENTIAL; and (e) a statement that provides in substance: "This envelope contains documents subject to a Protective Order of the Court. It should not be opened, nor its contents disclosed, revealed, or made public, except by Order of the Court." The party filing the designated Confidential Material with the Court shall indicate on service copies to opposing counsel which portions are filed under seal.

12. This Protective Order shall not preclude any party from: (a) claiming that any designated Confidential Material is not entitled to the protection of this Protective Order; (b) applying to the Court for an Order permitting the disclosure or use of documents, things, or information otherwise prohibited by this Protective Order; or (c) applying for an Order modifying this Protective Order in any respect.

13. The restrictions set forth in this Protective Order shall not apply to documents, things, or information that the parties agree, or the Court rules:

- a. has become public knowledge in a manner other than through a violation of this Order; or
- b. has been independently obtained by the non-designating party, as evidenced by written documentation.

14. For purposes of the Action or any other action, no party concedes that any Material designated by any other person as Confidential Material does in fact contain or reflect trade secrets or proprietary or confidential information. A party shall not be obligated to challenge the propriety of the designation of material as Confidential Material at the time made,

and failure to do so shall not preclude a subsequent challenge. If a Receiving Party seeks removal of protection for particular items of designated Confidential Material on the ground that such protection is not warranted under controlling law, the following procedure shall be used:

- a. The Receiving Party seeking such removal shall give counsel of record for the Producing Party notice thereof, in writing (by facsimile followed by a hard copy sent next business day courier), specifying the documents, things, or information for which such removal is sought and the reasons for the request. The Producing Party shall have ten (10) business days after receiving that notification within which to object to the removal of protection afforded by this Order. Any such objection shall be made in writing (by facsimile followed by a hard copy sent next business day courier). Failure to object within the requisite time limit is deemed a waiver of any claim to protection for that specific document, thing, or information under this Protective Order.
- b. If the parties, or the party and non-party, cannot reach agreement concerning the matter, then the Receiving Party seeking the removal of protection for designated Confidential Material must file and serve a motion with the Court; the designated material shall continue to be designated Confidential Material until the issue is resolved by Order of this Court or by agreement of the parties or the party and non-party.
- c. On any motions challenging the propriety of the designation of material as Confidential Material under this Protective Order, the Producing Party shall carry the burden of justifying the designation.

15. In the event that a Producing Party contends that documents or information that is subject to a claim of attorney-client privilege, work product immunity, or any other applicable privilege have been inadvertently produced, the fact of such production shall not constitute a waiver of such privilege(s) or immunity(ies). The following procedure shall apply to any claim for the return of such documents or information, and is without prejudice to the right of any party to apply to the Court for further protection or disclosure relating to discovery:

- a. The Producing Party shall promptly provide the Receiving Party with written notice identifying the documents or information subject to the attorney-client privilege, work product immunity, or otherwise immune from discovery that should have been withheld. Immediately after receiving such notice, the Receiving Party shall retrieve the original and all copies of information disseminated and shall not further copy or disseminate such documents or information.
- b. Upon receipt of the written notice described in Paragraph 16.a above, the Receiving Party shall return or destroy the documents or information identified by such written notice and all copies thereof (and certify in writing to such return or destruction) within seven (7) business days of receiving the Producing Party's written notice. The return of the document(s) and/or information to the Producing Party shall not preclude the Receiving Party from later moving the Court to compel production of the returned documents and/or information. No such challenge shall be premised upon a claim of waiver due solely to inadvertent production.

16. Upon final termination of the Action (including any appeal), unless otherwise

agreed to in writing by counsel for the Producing Party, each party shall within sixty (60) days assemble and return to the Producing Party or destroy all material designated as Confidential Material (and certify in writing to such destruction), including all copies, extracts, and summaries thereof, except that outside counsel may retain one (1) copy of deposition transcripts and exhibits, trial transcripts and exhibits, pleadings, and other materials that are of record in the litigation, subject to the confidentiality provisions of this Order. Counsel of record for all parties shall make certification of compliance herewith and shall deliver the same to opposing counsel of record not more than sixty (60) days after the final termination of the Action (including any appeal).

17. No part of the restrictions imposed by this Protective Order may be terminated, except by written stipulation executed by counsel of record for each Producing Party or by an Order of this Court for good cause shown. The terms of this Protective Order shall survive termination of the Action.

18. This Protective Order governs the confidentiality of designated Confidential Material before and after trial. If a party intends to disclose designated Confidential Material in Court at any pretrial proceeding open to the public, the issue of whether any such disclosure may be made shall be governed by applicable law or additional Order of this Court. That party, however, shall give counsel for the Producing Party notice of that intention, in writing (by facsimile followed by a hard copy sent next business day courier), at least two (2) business days before making such disclosure.

19. Notices under this Order shall be provided to the parties' respective counsel at their addresses indicated below, unless this provision is modified by the parties in writing.

For GSK: William McElwain and Michael Gordon
Wilmer Cutler Pickering Hale and Dorr LLP

The Willard Office Building
1455 Pennsylvania Ave., NW
Washington, DC 20004

For Teva: Jay Lefkowitz and Karen Robinson
Kirkland & Ellis LLP
655 15th Street, N.W.
Washington, DC 20004

20. This Protective Order shall not limit a party's examination, at a deposition, hearing or at trial, of persons who are not authorized to receive Confidential Material, so long as such examination concerns Confidential Material that the witness authored or previously had access to or knowledge of, as demonstrated by the Confidential Material itself or by foundation testimony during a deposition, hearing or trial. During deposition or trial testimony, counsel may disclose documents produced by a party to current employees and officers of the producing party. This Protective Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether he or she authored or previously had access to or knowledge of Confidential Material.

21. Nothing contained in this Order shall restrict or limit any Party's right to present Confidential Material to the jury or the Court during a trial or other hearing in the Action, and the parties shall take reasonable steps to maintain the confidentiality of such information at hearings and at trial in such manner as the Court may direct. The use of Confidential Material at trial shall be governed by the pretrial order.

22. No person subject to this Protective Order may disclose, in public or private, any Confidential Material designated by a party or non-party other than itself, except as provided for in this Protective Order. Nothing herein, however, shall affect the right of the Producing Party to disclose to its officers, directors, employees, consultants, or experts, any documents, things, or information designated by it as Confidential Material; such disclosure shall not waive the

protection of this Protective Order and shall not entitle other parties or their attorneys to disclose such information, documents, things, or information in violation of this Order.

23. Nothing in this Protective Order shall prevent or otherwise restrict counsel from rendering legal advice to the clients in this litigation and, in the course thereof, relying generally on examination of designated Confidential Materials; provided, however, that in rendering such advice and otherwise communicating with such client, counsel shall not disclose the specific contents of Confidential Materials to persons not authorized to receive such material pursuant to the Protective Order.

24. The Parties have agreed to the provisions of this Protective Order to facilitate the production of evidence that is potentially relevant in this Action. Neither the Parties' entry into this stipulated Protective Order, nor the designation of any material, document, thing, or other information as Confidential Material, nor the failure to so-designate any material, document, thing, or other information as Confidential Material, shall constitute evidence with respect to any issue in this Action.

25. If another court or an administrative agency subpoenas or orders production of any material designated as Confidential Material that a party has obtained under the terms of this Protective Order, such party shall respond setting forth the existence of this Protective Order, and notify the Producing Party of the pendency of such subpoena or Order within no more than five (5) days of receiving said subpoena or Order.

26. Any violation of this Protective Order may constitute a contempt of court and be punishable as such, and may subject the offending party or non-party to such additional and further remedies as may be available to the aggrieved party or non-party.

27. Until such time as this Protective Order has been entered by the Court, the parties

agree that upon execution by all of the parties, it will be treated as though it has been "So Ordered."

28. The Court retains jurisdiction subsequent to settlement or entry of judgment to enforce the terms of this Protective Order.

/s/ Patricia Smink Rogowski
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Attorneys for Defendants

IT IS SO ORDERED THIS _____ DAY OF _____ 2005.

Judge Gregory Sleet

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SMITH KLINE & FRENCH)
LABORATORIES LIMITED and)
SMITHKLINE BEECHAM)
CORPORATION d/b/a)
GLAXOSMITHKLINE,)
)
Plaintiffs,)
)
v.)
)
TEVA PHARMACEUTICALS USA, INC.,)
)
Defendant.)
_____)

Civil Action No. 05-197 _____

CONFIDENTIALITY UNDERTAKING

I, _____, declare hereby acknowledge that:

- (a) My current business address is _____.
- (b) My current employer is _____, and the address of my current employer is _____.
- (c) My current occupation or job description is _____.
- (d) I have received and carefully read the Stipulated Protective Order dated _____, and I understand its provisions. I will never use the contents of anything marked "Confidential Material" pursuant to the Protective Order, directly or indirectly, in competition with the disclosing party, nor will I permit others to do so. In addition, I understand that I must abide by all of the provisions of the Protective Order.
- (e) At or before the termination of this action, I will return to counsel for the party by whom I am employed or to counsel by whom I am employed all documents and other materials, including

notes, computer data, summaries, abstracts, or any other materials, containing or reflecting the Confidential Material that has come into my possession.

(f) I understand that I am subject to the jurisdiction of this Court for the purposes of enforcing the Protective Order, and I further understand that if I violate the provisions of the Protective Order, I will be in violation of a Court Order.

Date

Signature